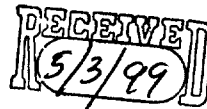




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April 26, 1999



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Liver powder may stimulate, support, and maintain protein metabolism. Carbamide stimulates osmotic transfer of body fluids helping to reduce swelling and also aids protein metabolism. Manganese is an important trace mineral for skeletal and connective tissue development. Vitamin E is a powerful anti-oxidant that protects the joints from damage by free radicals and increases joint mobility. Coenzyme Q10 increases tissue oxygenation to aid in repair of connective tissues. The combination of these ingredients contributes to the overall functioning and well-being of the skeletal system through a number of physiological processes.*
- (2) Ligaplex II helps to maintain a healthy skeletal system. Bone meal PMG™ extract is used to stimulate healing of connective tissue. Calcium is the most important element required for the body to maintain strong bones, teeth, and to trigger a number of other important physiological processes.*
- (3) Manganese is a trace mineral essential for the proper formation and maintenance of bone, cartilage, and connective tissues. Its properties for connective tissue formation aid in maintenance of articulating surfaces. Manganese is an anti-oxidant and cooperates with many different enzymes helping to carry out different metabolic processes, including energy production and protein metabolism.*

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- (4) Ligaplex II enhances metabolic efficiency. The liver in mammals is a glandular tissue, providing nutrients, enzymes, hormone precursors, and a number of other factors that help support specific cellular metabolism and physiological functions. The proteins found in the liver are used not only for a rich source of nutrients, but also to provide a nutritional stimulus to corresponding human organs. Carbamide stimulates proper tissue fluid metabolism. The maintenance of proper fluid levels in the interstitial spaces of tissues surrounding a joint helps to keep the joints healthy.*
- (5) Ligaplex II promotes cellular health. Veal bone PMG™ extract serves a myriad of functions beyond providing shape and support for the body. The antigenic properties of these nucleoprotein-mineral molecules promote healthy cellular division, growth, repair, and function.*
- (6) Protomorphogen™ extracts provide nutritional ingredients and support for the corresponding organs in human.*

These statements are made for a dietary supplement containing a proprietary blend of nutritional yeast, carbamide, bovine bone, veal bone PMG™ extract, bovine liver, defatted wheat (germ), bovine heart PMG™ extract, magnesium citrate, oat flour, inositol, carrot (root), dried peavine juice, Tillandsia usenoides, ribonucleic acid, beet (root), bovine spleen, ovine spleen, bovine adrenal Cytosol™ extract, bovine kidney, mushroom, bovine liver fat extract, flaxseed oil extract, potassium para-aminobenzoate, rice bran extract, and soy bean lecithin. Other ingredients include manganese glycerophosphate, gelatin, calcium lactate, water, calcium stearate, natural colors, mixed tocopherols, ascorbic acid, vitamin A palmitate, cellulose, cyanocobalamin and cholecalciferol. The name of the product is Ligaplex®II.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

